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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,730	04/23/2001	Michael R. Hufford	IVQ-003RCE	4534
959 7590 12/20/2007 LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			EXAMINER CASLER, TRACI	
			ART UNIT 3629	PAPER NUMBER
			MAIL DATE 12/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Office Action Summary</p>	Application No. 09/840,730	Applicant(s) HUFFORD ET AL.	
	Examiner Traci L. Casler	Art Unit 3629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 21-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 21-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to papers filed on October 21, 2007.

Claims 1, 22, 26, 33, 42, 47 and 51 have been amended.

Claims 1-18 and 21-51 are pending.

Claims 1-18 and 21-51 are rejected.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 17, 2007 has been entered

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-31 and 33-41 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,682,440; Karidis et al. Flexible Interface Portable Computing Device.

Hereinafter referred to as Karidis.

4. As to claims 1, 22, 26 and 51 Karidis teaches a system and apparatus with Paper form for recording data with an electronic instrument **incorporated into a paper diary** that generates a record regarding the use of the paper diary(form).(C. 13 I. 35-40).(C. 8 I. 1-3) **wherein said electronic instrument is incorporated into an outer casing of the paper diary and is hidden from view(Fig 11. 101(recording unit is in the Casing 208 and is hidden from the user under the paper forms 150.**

5. As to claims 2 and 23 interface for transferring records(C. 15 I. 41-47).

6. As to claims 3-7, 10-11, 28 and 32-37 Karidis teaches a system and apparatus with several options for sensors that detect use. (C. 7 I. 51-53 & C. 14 I. 51-53).

7. As to claims 8, 29-31 and 34-39-41 Karidis teaches time and date stamping a record when detection is made by recording unit(C. 10 I. 17-20)

8. As to claim 9 Karidis teaches superimposing the paper over the recording unit(C. 10 I. 1-5).

9. As to claim 12 Karidis teaches a pen to be used to allow a user to write on paper and contains a sensor(C. 1 I. 27-29).

10. As to claim 14 Kardis teaches storage for the electronic records(C. 6 I. 27-29).

11. As to claims 15-18 teaches the recording unit detecting use and date stamping(C. 10 I. 17-20):

12. As to claim 19 Karidis teaches the electronic instrument visible(Fig. 13).
13. As to claim 20 Karidis teaches a GI display(C. 6 I. 1-2).
14. As to claim 21 Kardis teaches the recording unit superimposed by the paper(covertly connected)(C.9 I. 59).
15. As to claim 24 Karidis teaches a cable connection(C. 6 I. 32-34).
16. As to claim 25 Karidis teaches device comprising a laptop(C. 7 I. 3-5).
17. As to claim 27 Karidis teaches the paper in communication with recording unit(C. 10 I. 17-20).

As to claim 33 Karidis teaches a method of detecting an event RELATED to data entry onto paper with an electronic instrument incorporated it diary(C. 15 I. 35-40) and capturing and storing CHARARCTERISTICS of the related event(C. 10 I. 1720). **wherein said electronic instrument is incorporated into an outer casing of the paper diary and is hidden from view(Fig 11. 101(recording unit is in the Casing 208 and is hidden from the user under the paper forms 150.**

18.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. Claims 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,362,440 Karidis et al. Hereinafter referred to as Karidis.

22. As to claims 47 Karidis teaches method of detecting an event RELATED to data entry onto paper with an electronic instrument incorporated it diary(C. 15 l. 35-40) and capturing and storing CHARACTERISTICS of the related event(C. 10 l. 17-20).)
wherein said electronic instrument is incorporated into an outer casing of the paper diary and is hidden from view(Fig 11. 101(recording unit is in the Casing 208 and is hidden from the user under the paper forms 150.Karidis fails to teach the data that is being entered/recorded or tracked as clinical trial data. However, it would be obvious to use the recording/computing device record any type of data that is pertinent to ones work or research area.

23. As to claim 48 Karidis teaches creating an electronic record(C. 10 l. 17-20).

24. Claims 42-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,362,440 Karidis as applied to claims 47-48 above, and further in view of Non-patent literature article "Diary keeping in asthma: comparison of written and electronic methods." Hyland, et al. Hereinafter referred to as Hyland.

25. As to claim 42 Karidis teaches detecting an event RELATED to data entry onto paper with an electronic instrument incorporated it diary(C. 15 I. 35-40) and capturing and storing CHARACTERISTICS of the related event(C. 10 I. 17-20). Karidis fails to teach comparing the electronic record with what the user wrote on paper. Hyland teaches a comparison of electronic and pencil diaries.(Abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to combine Hyland with Karidis as the electronic time coded diary provides an more accurate quality review of data entry, but the paper form is more desirable, comfortable or normal to the user.

26. As to claim 43-44 Karidis teaches time and date stamping a record when detection is made by recording unit(C. 10 I. 17-20)

27. As to claims 45-46 Karidis teaches time and date stamping a record when detection is made by recording unit(C. 10 I. 17-20). Karidis fails to teach validity of data based on time. However, Hyland teaches validity of a diary being completed the actual day rather than in retrospect(Pg. 1 C. 2.). It would have been obvious to one of ordinary skill in the art at the time of invention to combine Hyland with Karidis to be able to determine accuracy of data.

Response to Arguments

28. Applicant's arguments filed Claims 1-18 and 21-51 have been fully considered but they are not persuasive.

29. Applicants arguments are directed towards Kardis lacking a teaching of the "instrumented paper diary incorporated into an outer casing of the paper diary and is hidden from the subjects view. The examiner has noted Fig. 11 where Kardis shows the instrument for recording information containing "at least one " sheet of paper Ref 150 which is laid on casing 208, inside the casing is the recording unit 101 which is not able to be seen by the subject. The examiner notes applicants arguments are intending the apparatus to be a notebook similar to a pad of paper. However, the applicants limitations are written to be broadly interpreted. Additionally, the applicants disclosure for the teaching of the "paper diary" is not limited in what the structure can be. On page 7-8 the applicant discloses "the invention is not limited to The illustrated paper diary for recording pain and can comprise any format used to record information related to any number of subjects. Furthermore, the invention is not limited to the illustrated loose-leaf three-ring binder 11, and can comprise any suitable arrangement for recording information such as legal pad, folder, file and the like." Therefore, the structure of Kardis' apparatus has equivalent means for performing in a manner as claimed by applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traci L. Casler whose telephone number is 571-272-6809. The examiner can normally be reached on Monday-Thursday 6:00 am-4:30 pm.

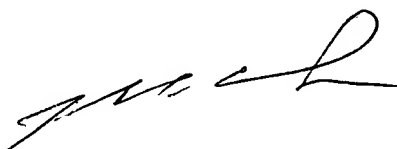
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on 571-272-6812. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLC



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